Serial No.: 10/077,566

Filed : February 15, 20

Filed: February 15, 2002

Page : 11 of 15

#### **REMARKS**

In the Office Action mailed December 27, 2007, all pending claims 1-17, 44, 48-52, 55 and 60-70 stand rejected. Applicants have amended each of the pending independent claims 1, 13 and 67, and have amended dependent claims 2-11, 14-17, 48-52, 55, 60-62 and 69 for consistency or clarity. In addition, Applicants have added additional dependent claims 71-75. Accordingly, claims 1-17, 44, 48, 52, 55 and 60-75 are pending. Applicants respectfully request reconsideration of the pending claims in view of the amendments above and the following remarks.

# Withdrawal of Rejections Under 35 USC 112, First Paragraph

The outstanding Office Action makes no Section 112 rejections, and thus Applicants understand that their remarks made previously were considered to be persuasive.

## Claim Rejections - 35 USC 102 and 103

The Office Action rejected claims 1, 3-12, 50, 63 and 65-68 under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent 5,353,800 to Pohndorf et al. ("Pohndorf"), or in the alternative, under 35 U.S.C. 103(a) as obvious over Pohndorf. The Office Action rejected the remaining claims under 35 U.S.C. 103(a) as obvious over Pohndorf in combination with various other references.

Without prejudice or admitting the correctness of the rejections, Applicants have amended each of the pending independent claims 1, 13 and 67 to define more particularly the subject matter sought to be patented. The amendments add no new matter. Support for the amendments is provided in Applicants' specification as originally filed, for example, in Figures 1C and 2A and paragraph 0055 of the published application (page 17, line 17 to page 18, line 4).

Applicants submit that each of the pending independent claims 1, 13 and 67 define subject matter that is patentable over Pohndorf and any of the other references of record, as do the pending dependent claims.

Serial No.: 10/077,566 Filed: February 15, 2002

Page : 12 of 15

Pohndorf discloses an implantable pressure sensor lead, wherein a hollow corkscrew-shaped (coiled) needle 16 extending from a distal end of the lead is coupled to a pressure transducer 14. (Abstract & Figure 1.) Pohndorf shows a sensor/needle assembly 10 of the lead in Figure 1, and in Figure 3 shows the coiled needle 16 screwed into myocardial tissue 36. Pohndorf discloses that the tissue 36 may be, for example, the ventricular septum of a patient's heart (col. 4, lines 60-61).

With respect to independent claim 1, Pohndorf does not, however, disclose or suggest the subject matter of claim 1, as amended. For Example, Pohndorf does not disclose or suggest, as recited in Applicants' claim 1 as amended, a method that makes use of "a pressure sensor assembly comprising a pressure transducer and a pressure transmission catheter," wherein a "proximal portion [of the pressure transmission catheter] is more crush resistant than [a] distal portion [of the pressure transmission catheter], and wherein the distal portion is more flexible than the proximal portion and has a degree of flexibility and radiused corners such that the distal tip is atraumatic." The Pohndorf device, by contrast, has a sharp, pointed tip 16' (Figures 1 and 3). Indeed, Pohndorf calls the structure 16 with the sharp, pointed tip 16' a needle. (Col. 3, line 30.) The tip 16' of the Pohndorf device is sharp and pointed because it is screwed into myocardial tissue 36 (Figure 3). (Col. 4, lines 59-60.)

In addition, Pohndorf does not disclose a method that includes "positioning the [pressure transmission] catheter so that the relatively crush resistant proximal portion is disposed in, and extends across a substantial portion of an entire distance of, a heart wall, and so that the relatively flexible distal portion is located substantially within a chamber of the heart." This is not the case in Figure 3 of Pohndorf. First, even if one were to consider, as set forth in the Office Action, Pohndorf's funnel-shaped adapter element 30 to be the claimed proximal portion, and the coiled needle 16 to be the claimed distal portion, the adapter element 30 does not meet the language of Applicants' claim 1 that recites that the "proximal portion is disposed in, and extends across a substantial portion of an entire distance of, a heart wall." Moreover, Pohndorf's coiled needle 16, with is contended to be the claimed distal portion, is not "located substantially within a chamber of a heart," as is recited of the distal portion in Applicants' claim 1.

Serial No.: 10/077,566
Filed: February 15, 2002

Page : 13 of 15

The Office Action contends, with respect to claim 1, that "the actual end of the catheter, i.e. the tip [16'], is weakened with respect to the body of the catheter [16], and as a result, the cap [30] is more crush resistant than the end [16'] of the coiled catheter [16]." Applicants respectfully submit that this contention is irrelevant, especially in view of the claim amendment. As mentioned above, the cap [30] does not meet the language of Applicants' claim 1 that recites that "proximal portion is disposed in, and extends across a substantial portion of an entire distance of, a heart wall." In addition, Pohndorf's tip 16' is not more flexible than the rest of the needle 16.

Finally, the Office Action contends, with respect to claim 1, that "[a]lternatively, since end cap 30 is placed in the heart wall and the tip [16'] is exposed, it would have been obvious to one skilled in the art to ensure that the cap 30 would be able to withstand more forces." Applicants respectfully disagree. There is no support in any reference of which Applicants are aware that supports such a contention. Indeed, there is no disclosure or suggestion in any reference of which Applicants are aware that it would be desirable for a tip of a catheter positioned within a heart to be more flexible than a portion of the catheter that extends across a heart wall.

Accordingly, Applicants submit that independent claim 1 defines subject matter that is patentable over Pohndorf, as do dependent claims 2-12, 44, 50-52, 55 and 60-66. As such, Applicants respectfully request that the anticipation and obviousness rejections of claims 1-12, 44, 50-52, 55 and 60-66 be withdrawn.

With respect to independent claim 13, Applicants submit that claim 13 is patentable over Pohndorf for the reasons described above in connection with claim 1. In addition, U.S. Patent No. 6,328,699, upon which the obviousness rejection of claim 13 was based in part, does not cure the deficiencies of Pohndorf. Accordingly, Applicants respectfully request that the obviousness rejection of independent claim 13 and dependent claims 14-17, 48-49 and 69-70 be withdrawn.

With respect to independent claim 67, Applicants submit that claim 67 is patentable over Pohndorf for the reasons discussed above in connection with claim 1. Accordingly, Applicants

Serial No.: 10/077,566 Filed: February 15, 2002

Page : 14 of 15

respectfully request that the anticipation rejections of independent claim 67 and dependent claim 68 be withdrawn.

## **New Dependent Claims 71-75**

New dependent claims 71-75 are added, as depending from claim 1, to claim more completely the subject matter sought to be patented. The new claims add no new matter. Support for the amendments appears in the specification appears in the specification as originally filed. For example, claims 71 and 72 are supported at least by FIGS. 5A and 5C and accompanying description; claims 71 and 73 are supported at least by FIGS. 6A-6E and accompanying description; claims 71 and 74 are supported at least by page 23, lines 15-23; claims 71 and 75 are supported at least by FIG. 3C and page 25, lines 20-22.

Claims 71-75 are patentable over the cited art for the additional reason that neither Pohndorf nor any other cited reference discloses the use of a structure for piercing the heart wall that is a separate structure from the pressure transmission catheter, as set forth in dependent claim 71 and in further detail in dependent claims 72-75. Accordingly, Applicants request that claims 71-75 be allowed.

#### Conclusion

Applicants submit that claims 1-17, 44, 48, 52, 55 and 60-75 are in condition for allowance, and request that the Examiner issue a notice of allowance.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Serial No.: 10/077,566 Filed : February 15, 2002

Page : 15 of 15

Examiner is authorized to charge Deposit Account No. 06-1050 \$60 for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Reg. No. 37,927

April 28, 2008 Stephen R. Schaefer

Fish & Richardson P.C. 60 South Sixth Street

**Suite 3300** 

Minneapolis, MN 55402 Telephone: (612) 335-5070 Facsimile: (612) 288-9696

60491519.doc